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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877

EXAMINER

MINNIFIELD, NTEAM

ARTICLE PAPER NUMBER

1645

DATE MAILED 02/05/2003

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,703

Applicant(s)

POLYAKOV ET AL

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Failure to Dismiss this Patent Application under 35 U.S.C. § 111(b) (PTO-893)
- 3) ☐ Notice of Informal Amendment (PTO-894)

DETAILED ACTION

Response to Amendment

1. Applicants' response filed December 2, 2002 is acknowledged and has been entered. Claims 1 and 2 are now pending in the present application. All prior art rejections (103 obviousness) have been withdrawn in view of Applicants arguments set forth in the December 2, 2002 response.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicants should update the status of all related applications; 09/256915 is now abandoned.
4. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a dermatomycosis vaccine comprising the inactivated dermatophytes as set forth in claim 1 (8 dermatophytes) and as set forth in claim 2 (3 dermatophytes). Applicants' representative (telephone conversation with Susan Pocchiari on May 24, 2002) has indicated that the vaccine must have all of the recited strains as set forth in the specification. The specification, at page 10, line 10, recites: "The vaccine which is applied is based on the following strains: [recited strains]". The specification, at page 11, line 10, recites: "[A]fter 2 days, 125 ml of each culture in suspension is taken and

mixed in a single container. The vaccine may be prepared by mixing together various combinations of the given strain." Exactly what was the composition of the vaccine administered that gave the results found in Tables 9 and 10? It is not clear if all 8 dermatophytes were used or some combination of 3, 4, 6 or 7 dermatophytes. It is not clear that the specific combination of 3 dermatophytes as set forth in claim 2 were used. It is not clear what dermatophyte(s) in the vaccine gave rise to the vaccine protection that is shown in Table 10. Does Applicant intend for "immunogenic response" to mean that vaccine protection has been established, see page 11?

The rejection is maintained for the reasons of record. Applicant's arguments filed December 2, 2002 have been fully considered but they are not persuasive. Applicants assert that the specification teaches how to make the vaccine preparation (Example 1) as well as immunizing the animals using the vaccine prepared in Example 1. Applicants further assert that the immunogenic response produced by immunization of an animal with a vaccine comprising a single inactivated strain, as described in Tables 1-7 establishes (results in) immunity to that strain.

However, the Examiner agrees that it is clear that the specification teaches how to make the claimed vaccine (combination of 8 different inactivated dermatophytes in a composition or a combination of 3 inactivated dermatophytes in a composition) by mixing each culture in a single container and mixing together the various combinations of the given cultures is set forth. However, it is not clear

which composition (all 8 cultures in one container or various combinations of less than 8 cultures and if less than 8 cultures specifically which ones) was used to generate the data found on tables 9 and 10 of the specification. Which cultures provide protection against ringworm infection in an animal? Does the vaccine comprising a combination of cultures protect in the same manner as the individual cultures; is there a synergistic affect with regard to protection against ringworm infection?

Gudding et al (Can. Vet. J., 1995) teaches that in animals vaccinated with inactivated vaccines, some protection is observed after challenge. However, the protective immunity is inadequate in most cases (abstract; p. 303, column 2). Further, the inactivated vaccine against ringworm must be capable of eliciting both humoral and cellular immune responses, of which the cellular response is crucial for protection and adjuvants are important in stimulating the cellular branch of the immune system (pp. 303-304). In view of the state of the art it is not clear if protection has been established against ringworm infection when Applicants state (see tables 1-7) "establishes immunity". It is not clear what type of immunity has been established. Applicants' vaccine composition does not recite a carrier or adjuvant, however Gudding indicates that the adjuvants are important in stimulating the cellular branch of the immune system and that the cellular branch is crucial for protection.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The

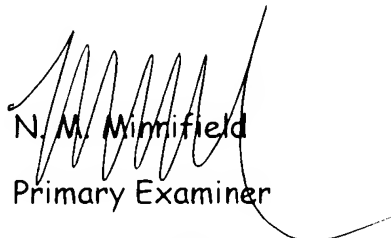
After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



N. M. Minnifield
Primary Examiner

Art Unit 1645

nmm

February 4, 2003